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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,730	01/05/2000	KOICHI SUGITA	4859-0029-0	9663
22850	7590	12/24/2003		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/477,730

Applicant(s)

SUGITA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-39 is/are pending in the application.
- 4a) Of the above claim(s) 21-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Amendment filed October 6, 2003, has been entered.

Claims 1-13 are cancelled.

Claims 14-39 are newly added and are pending.

Newly submitted claims 21-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly submitted claims 21-39 are directed to methods of expressing genes in plants wherein gene expression causes physiological abnormal behavior in a plant cell, whereas the originally presented invention was directed to vectors for introducing a gene into a plant wherein the vectors had a specific structural organization of selectable marker genes, with no particular reference to their effect on physiological behavior in a plant cell.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-39 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 14-20 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

***Claim Rejections - 35 USC § 112***

Claim 14, and claims 15-20 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth for claim 1 in the office action mailed May 7, 2003.

Applicant's arguments filed October 6, 2003, have been fully considered but they are not persuasive.

Applicant points out that like cancelled claim 1, newly added claim 14 specifies that "the desired gene is not a selectable marker gene", and argues that while there is no direct literal support for this limitation in the specification, one would conclude that the desired gene is not a selectable marker gene from the discussion of desired genes at pages 18-20 in the specification, since the vector already contains selectable marker genes.

The rejection is maintained because the limitation "wherein the desired gene is not a selectable marker gene" does not find support in the specification as originally filed, and thus constitutes new matter. The discussion of desired genes at pages 18-20 in the specification does not exclude desired genes that are selectable marker genes. Additionally, Applicant's own specification exemplifies a selectable marker gene as a desired gene (see for example page 30 lines 4-7 citing the NPTII gene as an example of a desired gene). Furthermore, the inclusion of multiple genes that may function as selectable marker genes in a single vector was known in the art at the time of Applicant's invention.

Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth for claims 1-5 and 7-13 in the office action mailed May 7, 2003.

Applicant's arguments filed October 6, 2003, have been fully considered but they are not persuasive.

Applicant argues that page 10 of the specification provides a detailed description of plant hormone signal transduction genes which can be used as a selectable marker gene, including several specific examples. Applicant further argues that by just providing the names of these genes the structural and functional description of these sequences is also provided because the genes were known in the art. Applicant additionally argues that the ability of these sequences to function as a selectable marker gene is an inherent property of the sequence itself.

The rejection is maintained because a representative number of combinations of plant hormone signal transduction genes and plant hormone synthesis genes that function together as selectable marker genes are not described. The mere recitation of specific genes known in the art to encode numerous different types of proteins involved in the transduction of signals initiated by numerous different types of plant hormones, and specific genes known in the art to encode numerous different types of proteins involved in the synthesis of numerous different types of plant hormones, does not describe the particular combinations of specific plant hormone signal transduction genes and specific plant hormone synthesis genes that would be able to function together as selectable marker genes in a plant transformation vector. Furthermore, while the

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ability of a protein encoded by a plant hormone signal transduction gene to transduce a signal initiated by a plant hormone may be an inherent property of the sequence itself, and while the ability of a protein encoded by plant hormone synthesis gene to participate in the synthesis of a plant hormone may be an inherent property of the sequence itself, the ability to function together as selectable marker genes is not inherent to all combinations of plant hormone signal transduction genes and plant hormone synthesis genes. In the instant case, Applicant has not described a representative number of species falling within the scope of the claimed genus, nor the structural features unique to the genus.

Claims 14-20 are rejected under 35 U.S.C. 112, because the specification, while being enabling a vector comprising a desired gene and the cytokinin synthesis gene *ipt* together with the cytokinin signal transduction gene CKI1 as selectable marker genes located within a removable DNA element, does not reasonably provide enablement for vectors comprising a desired gene and any unspecified plant hormone synthesis gene of any unspecified structure and function together with any unspecified plant signal transduction gene of any unspecified structure and function as selectable marker genes located within a removable DNA element, or for vectors comprising a desired gene and any unspecified plant hormone synthesis gene of any unspecified structure and function together with any unspecified plant cytokinin signal transduction gene of any unspecified structure and function as selectable marker genes located within a removable DNA element, or for vectors comprising a desired gene and any unspecified cytokinin synthesis gene of any unspecified structure and function together with any unspecified plant signal transduction gene of any unspecified structure and function as selectable marker

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genes located within a removable DNA element, for the reasons of record set forth for claims 1-5 and 7-13 in the office action mailed May 7, 2003.

Applicant's arguments filed October 6, 2003, have been fully considered but they are not persuasive.

Applicant argues that the specification provides a detailed description of how to make and use the claimed vector. Applicant also argues that the specification provides a detailed description of plant hormone signal transduction genes at page 10, that the working examples at pages 27-45 provide specific details regarding how to make the claimed vector and select the transformed tissue, and that one skilled in the art could, without undue experimentation, readily prepare and use other vectors within the scope of the claims.

The rejection is maintained because undue experimentation would be required to practice the full scope of the claimed invention. The specification does provide sufficient guidance for one skilled in the art to determine which particular combinations of the numerous different available plant hormone signal transduction genes and the numerous different available plant hormone synthesis genes could be used as selectable marker genes in a plant transformation vector. While the specification identifies a number of different known plant hormone signal transduction genes, and a number of different known plant hormone synthesis genes, the specification does not provide sufficient guidance with respect to which of these genes may be used in combination as a selectable marker genes, as the use of these genes in combination as selectable marker genes is unpredictable, and the specification discloses only one combination of a plant hormone signal transduction gene and plant hormone synthesis gene that may be used as

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a selectable marker genes in a plant transformation vector, the CKII cytokinin signal transduction gene in combination with the *ipt* cytokinin synthesis gene.

Applicant additionally argues that the Examiner is incorrect to assert that plant hormone signal transduction proteins would be detoxified, because the Examiner confuses degradation and detoxification, as degradation does not always involve detoxification, and detoxification does not always involve degradation. Applicant argues that one skilled in the art can easily understand that the protein is not subjected to detoxification in plant cells, and that proteins that function in signal transduction pathways are indispensable for growth and differentiation and would naturally be destined to exist in various plant cells.

As stated previously at page 10 of the office action mailed May 7, 2003, that degradation does not always involve detoxification, and detoxification does not always involve degradation is not disputed. However, while plant cells in general would be expected to contain proteins that function in plant hormone signal transduction pathways or in plant hormone synthesis at some point in time or under certain circumstances, the presence, amount and activity of any particular protein in any particular plant cell type at a specific time or under specific circumstances would depend on the metabolism of the protein in question in the cell type in question at the time in question or under the circumstances in question. This general principle applies to all proteins, including proteins that function in plant hormone signal transduction pathways and proteins that function in plant hormone synthesis.

Furthermore, Applicant's response does not address the additional variables that contribute to the unpredictability of any and all combinations of plant hormone signal

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transduction genes and plant hormone synthesis genes having the ability to function together as selectable marker genes in a plant transformation vector. Such variables were set forth at pages 5-9 of the office action mailed May 7, 2003 and include but are not limited to the structural and functional diversity of plant hormones, the structural and functional diversity of plant hormone biosynthetic enzymes, and the structural and functional diversity of the products of plant hormones signal transduction genes. The specification provides no guidance with respect to how to manipulate the effects of plant hormones other than cytokinins in order to select transformed plant cells, no guidance with respect to which plant hormone synthesis genes other than the cytokinin synthesis gene *ipt* to express in order to produce an effect that would be useful for the selection of transformed plant cells, and no guidance with respect to which plant hormone signal transduction genes other than the cytokinin signal transduction gene CKII1 to express in order to produce an effect useful for the selection of transformed plant cells. Accordingly, it would require undue experimentation for one skilled in the art to determine which combinations of plant hormone signal transduction genes and plant hormone synthesis genes to express simultaneously to manipulate a particular hormonal effect in order to select transformed plant cells.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 is indefinite in the recitation of "the selectable marker gene". It is unclear which selectable marker gene is being referred to, as the vector of claim 14 comprises

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two selectable marker genes, a plant hormone signal transduction gene and a plant hormone synthesis gene.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 is indefinite in the recitation of “the” site-specific recombination system. Use of the definite article “the” indicates that a particular site-specific recombination system is intended, but the claim makes no reference to which site-specific recombination system is “the” site-specific recombination system of claim 20.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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***Remarks***

No claim is allowed.

Claims 14-20 are deemed free of the prior art, due to the failure of the prior art to teach or suggest a vector comprising a desired gene and a plant hormone synthesis gene together with a plant signal transduction gene as selectable marker genes located within a removable DNA element.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
December 18, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180

1638  
*[Handwritten signature]*